**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| MYLAN PHARMACEUTICALS INC.,<br><br>Plaintiff,<br><br>v.<br><br>BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,<br><br>Defendants. | C.A. No. 23-556-RGA |



**REPORT AND RECOMMENDATION**

Defendants Bayer Intellectual Property GmbH, Bayer AG, and Janssen Pharmaceuticals, Inc. (collectively, "Defendants") moved to dismiss this action for lack of subject matter jurisdiction (D.I. 18, the "Motion") or, alternatively, to stay it pending the Federal Circuit's resolution of Defendants' appeal from a related decision by the Patent Trial and Appeal Board. (*Id.*) The issues have been fully briefed (D.I. 19, 25, 26) and I heard argument on November 8, 2023 ("Tr. ___"). For the following reasons, I recommend that the motion to dismiss be DENIED. Defendants' alternative request for a stay is DENIED.

## I. BACKGROUND

Plaintiff Mylan Pharmaceuticals Inc. ("Mylan") is attempting to market a generic version of Defendants' drug Xarelto®. Defendants hold the approved New Drug Application ("NDA") for Xarelto®, which contains the active ingredient rivaroxaban. (D.I. 2 at 1–2). Pursuant to the

Hatch-Waxman Act[1], Mylan submitted Abbreviated New Drug Application No. 212220 ("Mylan's ANDA") to the Food and Drug Administration ("FDA") seeking approval for Mylan's proposed 2.5 mg rivaroxaban tablets ("Mylan's ANDA Product"). (*Id.* ¶ 1). In connection with its ANDA, Mylan certified to Defendants' three Orange Book[2]-listed patents associated with Xarelto®'s 2.5 mg dosage strength: U.S. Patent No. 7,157,456 (the "'456 Patent"), U.S. Patent No. 9,415,053 (the "'053 Patent") and U.S. Patent No. 10,828,310 (the "'310 Patent"). (*Id.* ¶¶ 1, 4, 34; D.I. 25 at 6 n. 2).

Although Mylan's ANDA obtained tentative approval from the FDA on June 27, 2022 (D.I. 2 ¶ 37), final approval remains pending. As to the '053 Patent in which Mylan's ANDA certified under Paragraph IV[3], the parties agree that the '053 Patent should not bar FDA final approval because Defendants did not sue Mylan within 45 days of receiving Mylan's Paragraph IV notice.

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[1] The "Hatch–Waxman Act" is the "Drug Price Competition and Patent Term Restoration Act of 1984," Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat 2066 (2003) (hereinafter "MMA").

[2] The "Orange Book" an FDA publication "in which holders of New Drug Applications list all patents that may cover their products. *Lundbeck v. Apotex Inc.*, C.A. No. 18-88-LPS, 2020 WL 3507795, at *1 n.4 (D. Del. June 26, 2020) (citing 21 U.S.C. § 355(b)(1); *Dey Pharma, LP v. Sunovion Pharms. Inc.*, 677 F.3d 1158, 1159 (Fed. Cir. 2012)).

[3] "A Paragraph IV certification is an ANDA filer's statement that it intends to market its bioequivalent pharmaceutical product before the expiration of a patent listed as covering that product because the ANDA filer believes such patent is either not infringed or is invalid." *Lundbeck*, 2020 WL 3507795, at *1 n.2 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338–39 (Fed. Cir. 2003)).

(*Id.* ¶¶ 4–6; D.I. 19 at 5).[4] As to the '456 Patent in which Mylan's ANDA certified under Paragraph III,[5] the parties agree that the '456 Patent bars FDA final approval until its pediatric exclusivity[6] expires on February 28, 2025. (D.I. 2 ¶¶ 33–35; D.I. 19 at 3–4; D.I. 25 at 6). As for the '310 Patent, the parties do not appear to dispute that Mylan's ANDA can be approved notwithstanding that patent. (D.I. 25 at 6 n.2).[7] In view of these certifications, the parties seem to agree (or at least do not dispute) that only the '456 Patent should operate to block final approval of Mylan's ANDA until March 3, 2025—the first business day after the '456 Patent's pediatric exclusivity period expires on February 28, 2025. (D.I. 2 ¶¶ 33, 35; D.I. 19 at 3–4; D.I. 25 at 6).

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[4] Defendants had 45 days to sue Mylan for infringement of the '053 Patent and stay FDA approval for 30 months "so the infringement and validity questions can be worked out in court." *Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1118 (Fed. Cir. 2021) (citing 21 U.S.C. § 355(j)(5)(B)(iii)). That Defendants waited more than 45 days after they received notice relinquished their right to a stay but did not preclude from suing later for infringement. *Id.* (citations omitted). Nevertheless, the absence of a lawsuit means the FDA "shall" approve the ANDA "immediately." 21 U.S.C. § 355(j)(5)(B)(iii).

[5] "A Paragraph III certification is an ANDA filer's statement it will not market its bioequivalent pharmaceutical product until after expiration of a patent listed as covering that product." *Lundbeck*, 2020 WL 3507795, at *1 n.3 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(III); *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1374 (Fed. Cir. 2012)).

[6] If an NDA holder agrees to the FDA's request to perform pediatric studies subject to the FDA's approval, "the statute extends the period during which the FDA is barred from approving ANDAs filed by competing drug manufacturers for six months beyond the patent's expiration date"—that is, the pediatric exclusivity period. *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1341 (Fed. Cir. 2015) (citations omitted).

[7] As to the '310 Patent, Mylan's ANDA certified under Paragraph IV. (D.I. 25 at 6 n.2). Although Defendants sued Mylan (C.A. No. 22-1228-RGA (D. Del.), *consolidated into* C.A. No. 21-1742-RGA-JLH (D. Del.) at C.A. No. 22-1228-RGA, D.I. 40), Mylan asserts, and Defendants do not dispute, that Mylan's ANDA can be approved notwithstanding that patent because the "'310 Patent was not listed in the Orange Book in connection with Defendants' Xarelto® 2.5 mg tablets when Mylan submitted its ANDA." (D.I. 25 at 6 n.2).

Nevertheless, Mylan fears that the '053 Patent will stall final approval due to the unusual interplay of the patents' expiration dates and certifications. The '053 Patent will expire on November 13, 2024 during the '456 Patent's pediatric exclusivity period. (D.I. 2 ¶¶ 33, 36). When the '053 Patent expires, Mylan says that the FDA's "longstanding practice" will convert Mylan's Paragraph IV certification into a Paragraph II certification[8] and cause a new pediatric exclusivity period to attach to the '053 Patent, foreclosing final approval until May 13, 2025. (*Id.* ¶ 37; D.I. 25 at 7). This is 72 days after Mylan could have otherwise obtained approval (upon the '456 Patent's pediatric exclusivity expiration on February 28, 2025)—based on a patent that all parties agree Mylan doesn't infringe. (D.I. 25 at 1–2; Tr. 50:19–51:16).

To avoid this delay, Mylan filed suit on May 19, 2023 under the Hatch-Waxman Act's "civil action to obtain patent certainty" ("CAPC") to obtain a declaration of non-infringement of the '053 Patent (D.I. 2 ¶¶ 7–9).[9] Defendants then granted Mylan a covenant not to sue effective August 4, 2023 (D.I. 19-1, Ex. A at 1), but they have declined to waive pediatric exclusivity or stipulate to a consent judgment of non-infringement. (Tr. 6:6–7:2; D.I. 25 at 5, 8; D.I. 26 at 7). Defendants then filed this Motion, claiming that the Court lacks subject matter jurisdiction because they declined to file suit within 45 days of receiving Mylan's Paragraph IV letter and subsequently covenanted

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[8] A Paragraph II certification is an ANDA filer's certification that "such patent has expired." 21 U.S.C. § 355(j)(2)(A)(vii)(II).

[9] Created by Congress when amending the Hatch-Waxman Act by the MMA in 2003, the CAPC was "designed to prevent NDA holders from 'gaming' the Act by delaying the resolution of patent disputes with ANDA filers." *See Bristol-Myers Squibb Co. v. Mylan Pharms. Inc.*, C.A. No. 09-651-LPS, 2011 WL 13371929, at *2 (D. Del. July 18, 2011) (citations omitted). A CAPC permits an ANDA filer to sue the NDA holder to obtain a declaratory judgment that the Orange Book-listed patents subject to Paragraph IV certifications are invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(C).

not to sue Mylan for infringement of the '053 Patent. (D.I. 18; D.I. 19). In the alternative, Defendants seek a stay pending the Federal Circuit's resolution of Defendants' appeal in *Mylan Pharms. Inc. v. Bayer Pharma AG*, No. IPR2022-517 (P.T.A.B. July 28, 2023) concerning the '310 Patent. (*Id.*)[10]

## II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(1) permits the dismissal of a claim or an action for lack of subject matter jurisdiction. A Rule 12(b)(1) motion may be treated as either a facial or factual challenge to the court's subject matter jurisdiction. *See Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016). A facial attack contests the sufficiency of the pleadings, whereas a factual attack contests the sufficiency of jurisdictional facts. *See Lincoln Ben. Life Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). With respect to factual attacks,

> there is substantial authority that the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case. In short, no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims. Moreover, the plaintiff will have the burden of proof that jurisdiction does in fact exist.

*Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). Defendants' Motion is a factual attack on subject matter jurisdiction. (D.I. 19 at 6).

Federal courts have jurisdiction over a CAPC brought by Paragraph IV ANDA filers against NDA holders "to the extent consistent with the Constitution"—that is, to the extent such disputes present an Article III case or controversy. *Teva Pharms. USA, Inc. v. Novartis Pharms.*

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[10] While a motion to dismiss for lack of subject matter jurisdiction is dispositive, a motion to stay is non-dispositive. *See Applied Biokinetics LLC v. KT Health, LLC*, C.A. No. 22-638-RGA-JLH, 2023 WL 6387679, at *1 (D. Del. Sept. 29, 2023). Because Defendants' instant motions implicate both non-dispositive and dispositive requests, I have titled this opinion a Report and Recommendation.

*Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007); *see also MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). The Supreme Court has held that a "case or controversy" exists when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127. Informing *MedImmune*'s "all the circumstances" test are justiciability doctrines involving standing, ripeness, and mootness, because "satisfying these doctrines represents the absolute constitutional minimum for a justiciable controversy" under Article III. *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1278 (Fed. Cir. 2014) (internal citations and quotation marks omitted). In other words, a declaratory judgment action is "justiciable under Article III only where (1) the plaintiff has standing, (2) the issues presented are ripe for judicial review, and (3) the case is not rendered moot at any stage of the litigation." *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008) (internal citations omitted).

## III. DISCUSSION

### A. Whether this Court Has Subject Matter Jurisdiction

Defendants have moved to dismiss Mylan's action on two grounds. First, Defendants argue that this Court lacks subject matter jurisdiction because the covenant not to sue "extinguishes any case or controversy over the '053 Patent." (D.I. 19 at 6). Second, Defendants argue that Mylan's "speculations" about future FDA conduct cannot establish jurisdiction. (*Id.* at 8). For the following reasons, I disagree.

*1. The covenant not to sue does not divest this Court of subject matter jurisdiction.*

In considering Defendants' arguments with respect to the covenant's operation in this case, it would not be unreasonable to understand Defendants' argument on subject matter jurisdiction to

be, essentially, one of mootness. That is, "[u]nder what circumstances can the unilateral actions of one party divest a court of jurisdiction?"[11] *Sanofi v. Lupin Atlantis Holdings Sa*, C.A. No. 15-415-RGA, 2017 WL 384062, at *1 (D. Del. Jan. 26, 2017); *Dey*, 677 F.3d at 1165 ("While Article III requires that 'an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed,' the question of whether a controversy exists at a later stage of the proceeding is governed by mootness doctrine."). "[A] case is moot when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Caraco*, 527 F.3d at 1296 (quoting *Powell v. McCormack*, 395 U.S. 486, 496–97 (1969)).

Here, regardless how Defendants' argument is packaged, I conclude that Defendants' covenant not to sue does not "extinguish" any case or controversy over the '053 Patent. In arguing

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[11] Defendants shy away from categorizing their argument as one of mootness, saying that it is "irrelevan[t]" because "There is no dispute between Mylan and Defendants; thus, there is nothing to moot." (D.I. 26 at 9 n.3). It is possible that Defendants retreat from mootness in view of the Federal Circuit's contrary pronouncement in *Dey*. *See Dey*, 677 F.3d at 1164 ("Sunovion does not attempt to argue that its covenant not to sue Dey over the '289 patent moots this case, as that argument is foreclosed by our contrary holding in *Caraco*."). I nevertheless observe that Defendants in their briefing used the phrase "extinguish" to describe the impact of the covenant not to sue, which seems to impliedly concede that jurisdiction existed when Mylan initiated this action under CAPC. At argument, however, Defendants sidestepped the question and instead seem to suggest that that subject matter jurisdiction never existed by casting Mylan's Complaint as premised on speculation:

> THE COURT: So is it your position, just to be very clear, that when the case was filed by Mylan, jurisdiction existed and by extending the covenant not to sue the defendants extinguished the jurisdiction?
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> MR. PICOZZI: So I don't believe we necessarily have to go that far. I think it is enough to say that as it stands right now there's certainly no jurisdiction. I think that even at the beginning of the case there is still a question of whether or not there would have been jurisdiction given the speculative nature of Mylan's action which depends on FDA's supposed actions, which are not tethered to anything.

(Tr. 11:7–21).

otherwise, Defendants principally rely on non-Hatch-Waxman Act authority arising in ordinary infringement actions. (D.I. 19 at 6–7) (citing *Super Sack Manufacturing Corp. v. Chase Packaging Corp*, 57 F.3d 1054, 1059–60 (Fed. Cir. 1995) (holding that an unconditional promise not to sue "for infringement as to any claim of the patent-in-suit based upon products currently manufactured and sold . . . was sufficient to divest the court of jurisdiction over . . . counterclaims for noninfringement."); *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1282 (Fed. Cir. 2010) (holding that, when patentee sold all interests in asserted patents to plaintiff and later represented that patentee "will waive any rights it may have, if any, separate and apart from any rights it has transferred to the new patent owners, to pursue any damages or relief from [defendant]," no case or controversy existed between patentee and defendant); *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1349 (Fed. Cir. 2010) (holding covenant not to sue extinguished any current or future case or controversy between the parties even if conserving judicial resources and "protecting the legal system against manipulation by parties" encouraged judicial intervention); *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1345–48 (Fed. Cir. 2007) (holding that pretrial tender of covenant not to sue divested district court of subject matter jurisdiction); *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999) ("[A] covenant not to sue for any infringing acts involving products 'made, sold, or used' on or before the filing date [of a complaint] is sufficient to divest a trial court of jurisdiction over a declaratory judgment action.")). Although Defendants maintain that, "[n]othing warrants departure from those principles here," (D.I. 19 at 8), courts considering subject matter jurisdiction in the Hatch-Waxman context have consistently rejected the argument that a covenant not to sue renders a declaratory judgment action categorically non-justiciable. *See, e.g.*, *Dey*, 677 F.3d at 1164; *Mylan Pharmaceuticals Inc. v. Janssen Pharmaceuticals, Inc.*, C.A. No. 15-2990, 2015 WL 13203464, at *1–2 (E.D. Pa. Aug. 21, 2015);

*Purdue Pharm. Prods., L.P. v. Actavis Elizabeth, LLC*, C.A. No. 12-5311-JLL, 2014 WL 1394178, at *4–9 (D.N.J. Apr. 9, 2014); *Shire LLC v. Impax Labs., Inc.*, C.A. No. 10-05467-RS, 2012 WL 12919474, at *3–5 (N.D. Cal. Aug. 20, 2012); *Seattle Children's Hosp. v. Akorn, Inc.*, C.A. No. 10-5118-RMD, 2011 WL 6378838, at *3–9 (N.D. Ill. Dec. 20, 2011).

For example, in *Caraco*, the Federal Circuit held that a covenant not to sue conveyed by an NDA holder (Forest) to a subsequent Paragraph IV ANDA filer (Caraco) did not divest the court of subject matter jurisdiction over Caraco's action seeking a declaration of invalidity or non-infringement in order to trigger a first-filer's 180-day exclusivity period. *Caraco*, 527 F.3d at 1291–97.[12] Concluding that Caraco had standing, the Federal Circuit explained that Forest's actions "potentially exclud[ing] non-infringing generic drugs from the market" amounted to a judicially cognizable injury-in-fact that arose because of Forest's decision to list the asserted patent in the Orange Book, and such injury could be redressed by a declaratory judgment that would "clear the path to FDA approval that Forest's actions would otherwise deny Caraco." *Id.* at 1292–93. Critically, the Federal Circuit held that the declaratory judgment action was not mooted by Forest's covenant not to sue Caraco over the patent at issue:

> To be sure, Forest's covenant not to sue eliminates any reasonable apprehension of suit on the '941 patent. If a threat of suit was the only action allegedly taken by Forest that effectively excluded Caraco from the marketplace, the covenant not to sue would moot Caraco's case and divest the district court of Article III jurisdiction. However, Caraco does not only allege that it has a reasonable apprehension of suit on the '941 patent. Caraco also alleges that the listing of the '941 patent in the Orange Book effectively prevents Caraco from entering the drug market. Essentially, Caraco is alleging that it has been denied entry to the market in a manner that is unique to the Hatch-Waxman context.

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[12] Although *Caraco* was decided under the pre-2003 version of the Hatch-Waxman Act and not under the current version, Defendants do not dispute *Caraco*'s applicability on this ground.

> Clearly, in the ordinary infringement context, even when a patentee maintains that its patents are valid and infringed by a potential defendant, a covenant not to sue allows the recipient to enter the marketplace . . . However, in the Hatch-Waxman context, regardless of a covenant not to sue, a generic drug manufacturer cannot enter the market without FDA approval . . .
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> In sum, Caraco's declaratory judgment action presents an Article III controversy as to whether the drug described in Caraco's ANDA infringes Forest's Orange-Book listed '941 patent . . . because Forest's actions effectively prevent the FDA from approving Caraco's ANDA and thus exclude Caraco from the drug market. Forest's covenant not to sue does not eliminate the controversy with Caraco, because the controversy can only be resolved by a judgment that determines whether Forest's '941 patent is infringed by the drug described in Caraco's ANDA. Accordingly, we hold that this action presents an ongoing Article III case and controversy.

*Caraco*, 527 F.3d at 1296–97. Here, because Mylan is alleging that it will be denied entry to the market in a manner unique to the Hatch-Waxman context, I am compelled to apply the principles underlying *Caraco* and its progeny over Defendants' cited authority arising in ordinary infringement actions.

Applying those principles, I conclude that, even if Defendants' covenant not to sue extinguished any reasonable apprehension of suit, the '053 Patent remains a barrier to Mylan's market entry and accordingly gives rise to a justiciable case or controversy, particularly as Defendants have refused to stipulate to a consent judgment of non-infringement or selective waiver.[13] Unlike a covenant not to sue, a judgment of non-infringement could accelerate Mylan's

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[13] While Defendants have tendered a covenant not to sue, they have declined to stipulate to a judgment of non-infringement or waive pediatric exclusivity as to the '053 Patent, impliedly conceding a gap in the rights that flow from each. Defendants acknowledge a "practical and legal distinction" between a covenant not to sue and a court judgment but decline to elaborate as their effects. (Tr. 6:12–7:2). Instead, Defendants maintain requiring a judgment of non-infringement under these circumstances is "not fair." (Tr. 6:12–7:2) ("[T]he judgment that Mylan

market entry because, as Mylan points out, at least one court has recognized that when a party "prevails" in underlying infringement litigation, such judgment of non-infringement could accelerate the timing of final approval under circumstance analogous to what Mylan faces here. *See Mylan Lab'ys, Inc. v. Leavitt*, 484 F. Supp. 2d 109, 120 (D.D.C. 2007) (noting that FDA deviated from its "longstanding practice" to convert a Paragraph IV certification into a Paragraph II certification and accordingly declined to enforce the patent's pediatric exclusivity period after concluding that the Hatch-Waxman Act "manifests a clear Congressional intent that pediatric exclusivity not block the approval of an ANDA where the ANDA applicant has *prevailed* in the paragraph IV patent litigation") (emphasis added). Defendants maintain that *Leavitt* merely highlights that the FDA retains discretion as to when to approve Mylan's ANDA and that "there is no reason to believe that FDA will require a court judgment of non-infringement regarding the '053 Patent or selective waiver." (D.I. 26 at 1–2, 7). But Defendants cannot seriously dispute that, if Mylan were to obtain a judgment of non-infringement on the '053 Patent prior to November 13, 2024, Mylan would have "prevailed" in its CAPC action, accelerating the timing of final approval to after February 28, 2025 (when pediatric exclusivity as to the '456 Patent expires), rather than after May 13, 2025 (when pediatric exclusivity as to the '053 Patent expires). Thus, I do not find that Defendants' covenant extinguishes their controversy with Mylan.

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is seeking in this case requires court action in the first place, which we think shouldn't have been brought. We think that as a private party that is not involved in Mylan's dispute with FDA that, we should not have been sued and we shouldn't be dragged into court. It's not fair to us and it's also not fair to the Court. And it's also not . . . fair to the agency that is put in the position of not having a chance to articulate any kind of view on the ultimate issue of whether or not Mylan's product should be approved under the circumstance given the covenant not to sue."). Given that Mylan has invoked its right to a declaratory judgment of non-infringement consistent with CAPC and that the '053 Patent remains listed, I do not discern any "unfairness" that would dispositively favor Defendants' Motion.

Defendants insist that *Caraco* does "not support the Court's exercise of jurisdiction" because it involved the statutory right to trigger a first-filer's 180-day exclusivity period by a court judgment, and no such statutory analog exists here. (D.I. 19 at 12–13; D.I. 26 at 7–8). Mylan concedes that it is aware of no authority extending *Caraco* to circumstances beyond those involving triggering a first-filer's 180-day exclusivity period. (Tr. 39:19–20). But to favor Defendants' somewhat formalistic view would require me to ignore the reasoning of *Caraco* emphasizing that a case or controversy exists when a listed patent creates an exclusivity barrier to FDA approval despite a covenant not to sue. And, Defendants have not provided me with any other authority to conclude that this principle should not apply with equal force to the '053 Patent's pediatric exclusivity.

*2. Mylan's claim is not improperly speculative.*

Defendants next argue that Mylan's declaratory judgment claim improperly rests on "Mylan's speculation about what FDA might do, despite the absence of any affirmative indication in its favor." (D.I. 26 at 8). According to Defendants, when the '053 Patent expires on November 13, 2024, no statute or rule will compel the FDA to forestall final approval either by converting Mylan's Paragraph IV certification into a Paragraph II certification, or by enforcing the '053 Patent's pediatric exclusivity period against Mylan. (*Id.*; Tr. 50:6–18). Therefore, Defendants maintain that "Mylan's jurisdictional assertion rests on its speculative and unsupported prediction about FDA's discretionary actions." (D.I. 26 at 8).

The case-or-controversy analysis, as relevant here, "has borrowed from decisions on standing and ripeness." *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1362 (Fed. Cir. 2015) (citations omitted). Article III standing requires "[a] plaintiff [to] allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested

relief." *Novartis*, 482 F.3d at 1337 (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)). Where, as here, no further facts are needed for the requested adjudication (non-infringement is beyond dispute given Defendants' concessions and the covenant not to sue), "ripeness depends on any harm to [Mylan] from delaying adjudication and the degree of uncertainty about whether an adjudication will be needed." *Apotex*, 781 F.3d at 1362. "Withholding court consideration of an action causes hardship to the plaintiff where the complained-of conduct has an 'immediate and substantial impact' on the plaintiff." *Caraco*, 527 F.3d at 12995 (quoting *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 171 (1967)).

As an initial matter, Defendants' characterization of Mylan's concerns as based on "nothing other than speculation" is at odds with multiple cases signaling otherwise. In *Ranbaxy*, the United States District Court for the District of Columbia noted that:

> [at the moment of patent expiry,] the Paragraph IV certification became invalid, and either converted as a matter of law to Paragraph II certifications or became inaccurate, thereby creating both an obligation on [the ANDA holder's] part to amend its ANDAs to reflect patent expiry and an inability on the part of the FDA to approve the ANDAs in their inaccurate form.

*Ranbaxy Lab., Ltd. v. FDA*, 307 F. Supp. 2d 15, 21 (D.D.C. 2004), *aff'd*, 96 Fed. Appx. 1, 2004 WL 886333 (D.C. Cir. 2004). Other courts are in accord. *See Mylan Lab'ys, Inc. v. Thompson*, 332 F. Supp. 2d 106, 122 (D.D.C. 2004), *aff'd*, 389 F.3d 1272 (D.C. Cir. 2004) ("Consistent with the *Ranbaxy* court holding, as of midnight on July 23, 2004, when [the NDA holder's] patent expires, [the ANDA holder] had to either amend its ANDA and substitute a paragraph II certification for its paragraph IV certification or the FDA could treat [the ANDA holder's] paragraph IV certification as a paragraph II certification."); *Leavitt*, 484 F. Supp. 2d at 120 (noting that courts have "upheld the FDA's longstanding practice to deem paragraph IV certifications as paragraph II certifications upon patent expiration"). Although Defendants note that the *Leavitt*

court recognized that the FDA may "depart" from its typical practice to convert Paragraph IV certifications into Paragraph II certifications when "peculiar circumstances" warrant (D.I. 26 at 1 (citing *Leavitt*, 484 F. Supp. 2d at 121)), Defendants provide no authority or serious argument that the FDA under these circumstances will wield its discretion to favor Mylan.[14]

Turning to standing, I decide in Mylan's favor.[15] Although Defendants seem to suggest any alleged injury to Mylan would be inflicted by the FDA,[16] the Federal Circuit has consistently held that "the alleged action taken (giving rise to the injury-in-fact) [is][the] listing [of] particular patents in the Orange Book." *Teva Phams., USA, Inc. v. Esai Co. Ltd.*, 620 F.3d 1341, 1345 (Fed. Cir. 2010), *vacated on procedural grounds by Teva Pharms. USA, Inc. v. Eisa Co. Ltd.*, 131 S.Ct. 2991 (2011) (citing *Caraco*, 527 F.3d at 1292; and *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1359–60 (Fed. Cir. 2008)). In *Caraco*, the Federal Circuit concluded that a subsequent ANDA filer had a judicially cognizable injury-in-fact because a judgment of non-infringement or invalidity "would eliminate the *potential* for the [listed patent] to exclude Caraco from the drug market." *Caraco*, 527 F.3d at 1293 (emphasis added). Here, the '053 Patent remains listed in the Orange Book and a judgment of non-infringement would allow timely approval of

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[14] Defendants point to draft guidance published by the FDA in May 2023 stating that the FDA will refuse to approve an ANDA based on pediatric exclusivity if (1) the ANDA applicant "did not seek approval until the end of the patent term," (2) "its challenge has been unsuccessful," or (3) it "files a paragraph IV certification challenging a listed patent, and the patent litigation is ongoing when the patent expires." (D.I. 26-1, Ex. A, at 29–30 n.122). While the guidance generally discusses pediatric exclusivity, it remains in draft form and it does not address cascading patent expiration dates and any attendant conversions. As a result, I do not find it dispositive here.

[15] Although Mylan asserts it has standing (D.I. 25 at 13), Defendants do not explicitly reference standing or otherwise seem to contest it, other than by arguing that Mylan's "injury" is "speculative." (D.I. 26 at 6–9).

[16] *See* D.I. 26 at 7 ("any injury that Mylan suffers will occur as a result of FDA's refusal to approve Mylan's ANDA after the '456 Patent's pediatric exclusivity expires based on the '053 Patent's pediatric exclusivity").

Mylan's ANDA. *Id.* at 1292–93; *cf. Shire*, 2012 WL 12919474, at *5 ("Here, it is enough to satisfy jurisdiction pursuant to the Declaratory Judgment Act that a declaration of non-infringement would remove the '290 patent as a stumbling block to market entry under the Hatch-Waxman framework.").[17]

Turning to ripeness, I conclude Mylan's action is ripe. Because Mylan "has a complete generic drug product that has been submitted to the FDA for approval," additional factual development would not help this Court determine whether Mylan's ANDA Product "infringes the claims of" the '053 Patent. *See Caraco*, 527 F.3d at 1295 (holding that later ANDA filer's claims satisfied the fitness prong of the ripeness test because the later ANDA filer's "generic drug product . . . [had] been submitted to the FDA for approval, and no additional facts [were] required to determine whether this drug infringe[d] the claims of" the NDA filer's patent). Moreover, withholding consideration of Mylan's declaratory judgment action has the "immediate and substantial impact" of forestalling Mylan's ability to demonstrate to the FDA that it is a prevailing party in non-infringement litigation to avoid enforcement of the '053 Patent's pediatric exclusivity period. *Leavitt*, 484 F. Supp. 2d at 120. Depriving Mylan of that ability could result in Mylan losing profits during a time it was excluded from the market by a patent that all parties agree Mylan does not infringe. *See Caraco*, 527 F.3d at 1295–96 ("Thus, if Caraco's drug does not infringe Forest's '941 patent, then delaying court consideration of Caraco's declaratory judgment action on the '941 patent delays the date on which the FDA is authorized to approve Caraco's ANDA.

[17] The Federal Circuit arrived at a contrary outcome in *Janssen*, concluding that an ANDA holder had no cognizable injury when it stipulated to the infringement, validity, and enforceability of another Orange-Book listed patent. 540 F.3d at 1356. Here, Defendants do not argue that Mylan has stipulated to the validity, infringement, and enforceability of a patent that would bar Mylan's market entry regardless of this suit, so I do not consider *Janssen* to be controlling on this ground.

Specifically, Caraco would be delayed until at least 181 days after the '712 patent expires in 2012. Because Caraco cannot market its generic drug without FDA approval, being delayed from resolving its claim to noninfringement of the '941 patent creates a potential for lost profits. Accordingly, Caraco's action is ripe for judicial review."); *Purdue*, 2014 WL 1394178, at *9 (citation omitted). Thus, under these circumstances, delay in resolving Mylan's claim will have an immediate and substantial impact on Mylan.

Although Defendants maintain that Mylan must wait for an unfavorable FDA decision as a condition precedent to asserting jurisdiction over Mylan's claims, such a requirement would undermine the Hatch-Waxman Act's policy of encouraging "early resolution of patent disputes" and congressional intent supporting "the need for broad federal jurisdiction over [civil actions to obtain patent certainty]." *See Caraco*, 527 F.3d at 1285; *cf. Purdue*, 2014 WL 1394178, at *6 (rejecting argument that later ANDA filer must obtain tentative approval from FDA before declaratory judgment claims regarding patents over which the patent holder has granted a covenant not to sue are justiciable); *Akorn*, 2011 WL 6378838, at *8 (same). A civil action to obtain patent certainty "specifically permits an ANDA applicant to file a declaratory judgment action under 28 U.S.C. § 2201 against the patent owner or the brand-name drug company 'for a declaratory judgment that the patent [listed in the Orange Book] is invalid or will not be infringed by the drug' covered by the ANDA" once it notifies the NDA holder of its Paragraph IV ANDA, makes the statutory offer of confidential access, and 45 days pass without the NDA holder suing the ANDA holder for infringement. *Novartis*, 482 F.3d at 1342 (quoting 21 U.S.C. § 355(j)(5)(C)).

Defendants do not argue that Mylan failed to satisfy any of these statutory requirements.[18]

Defendants state that "Mylan's supposed injury has nothing to do with Defendants" because "were Defendants to suffer an injury based on FDA's application of pediatric exclusivity, their recourse would be to sue FDA under the APA, not under the Patent Act, which supplies no such right." (D.I. 19 at 2). But *Caraco* and its progeny have rejected such a requirement. In *Shire*, for example, an NDA holder dedicated an asserted patent to the public domain and sought to amend its complaint to withdraw infringement claims related to that patent. *Shire*, 2012 WL 12919474, at *2–5. The defendant ANDA holders opposed the NDA holder's amendment because they had counterclaimed and sought a declaration of non-infringement on the asserted patent. *Id.* The court disagreed that the patent's dedication to the public mooted the NDA holder's infringement claims, noting that "the Federal Circuit has repeatedly found that the elimination of the threat of an infringement suit does not necessarily defeat jurisdiction under the Declaratory Judgment Act where barriers to market entry remain for generic drug companies." *Id.* at *3 (citing *Caraco*, 527 F.3d at 1296–97)). The court specifically noted that, "to the extent [the NDA holder] suggests [the ANDA holders] have failed to avail themselves of all administrative remedies before the FDA, there is no such requirement." *Id.* at *5. Defendants have no answer to *Shire* other than calling it a "unique situation" that "does not support Mylan." (D.I. 26 at 8).

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[18] When asked at argument why the existence of any uncertainty was not sufficient to create subject matter jurisdiction consistent with CAPC, Defendants appeared to condition CAPC jurisdiction on whether such certainty was "reasonable," characterizing Mylan's claim to uncertainty as "not reasonable because they haven't provided any evidence as to how FDA will rule." (Tr. 19:17–20:17). Defendants do not provide any authority to support this position and I do not understand the statue to condition Mylan's entitlement to a judicial finding of non-infringement by providing such evidence.

The Federal Circuit's recent decision in *Apotex, Inc. v. Daiichi Sankyo, Inc.* further undermines Defendants' framing of this action as a dispute between Mylan and the FDA. 781 F.3d at 1359. In *Apotex*, the court exercised subject matter jurisdiction over an ANDA filer's (Apotex) action seeking a judgment of non-infringement even when the NDA holder (Daiichi) had disclaimed the patent at issue and requested that the FDA delist it. In rejecting Daiichi's contention that its statutory disclaimer means "there is no adversity between it and Apotex over stakes of a concrete character," the Federal Circuit explained:

> The concrete stakes over which Daiichi and Apotex are fighting are the revenues to be earned through selling olmesartan medoxomil. The patent disclaimer eliminates one, but only one, potential legal barrier to Apotex's ability to make such sales sooner rather than later. The listing of the patent, with its current consequence of preventing FDA approval during [the first filer's] presumptive exclusivity period, is another, and the parties have adverse concrete interests in the truncation or preservation of that period.

*Id.* at 1362. So too here. Thus, following *Apotex*, Defendants and Mylan have "substantial, concrete stakes in whether [Mylan] secures the non-infringement judgment it seeks to advance its entry into the market" because the judgment issues, "there is every likelihood that [Defendants] will lose substantial revenues" and [Mylan] will gain substantial revenues" by entering the market once the '452 Patent's exclusivity period expires. *Id.* at 1363. Under these facts, then, "this case is quite different from cases in which a case or controversy has been held missing because the plaintiffs had mere generalized or bystander interests in others' compliance with law." *Id.*

* * *

I conclude that "under all the circumstances" there is a "substantial controversy" between Defendants and Mylan who have "adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment" and do not recommend dismissing this action for

lack of subject matter jurisdiction. *MedImmune*, 549 U.S. at 127 (internal quotation marks and citation omitted).[19]

**B. Defendants' Motion to Stay Is Denied**

In the alternative, Defendants ask the Court to stay this action pending the Federal Circuit's resolution of Defendants' appeal in *Mylan Pharms. Inc. v. Bayer Pharma AG*, No. IPR2022-517 (P.T.A.B. July 28, 2023) concerning the '310 Patent. (D.I. 19 at 14).

In determining whether to grant a stay, the court considers "(1) whether granting the stay would simplify the issues in question and the trial of the case; (2) the status of the district court litigation, particularly whether discovery is complete and a trial date has been set; and (3) whether the stay would cause the non-movant to suffer undue prejudice or allow the movant to gain a clear tactical advantage." *IOENGINE, LLC v. PayPal Holdings, Inc.*, C.A. No. 18-452-WCB, 2020 WL 6270776, at *2 (D. Del. Oct. 26, 2020) (citations omitted). "Courts in this district have typically denied motions to extend stays after a ruling from the PTAB, emphasizing the difference between the circumstances before and after the PTAB issued its decision and how that difference in circumstances cuts against an extension of the stay." *IOENGINE*, 2020 WL 6270776, at *2 (citing *Dermafocus LLC v. Ulthera, Inc.*, C.A. No. 15-654, 2018 WL 5113960, at *2 (D. Del. Oct. 19, 2019) ("[W]hile the Federal Circuit may come to a different conclusion than the PTAB, the mere

[19] In the alternative, Defendants argue this Court should discretionarily decline jurisdiction under the Declaratory Judgment Act. (D.I. 19 at 13). Although "the trial court has significant discretion in determining whether or not to exercise declaratory judgment jurisdiction" even if a case or controversy exists, *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1328 n. 3 (Fed. Cir. 2012), "[t]he use of discretion is not plenary . . . for there must be well-founded reasons for declining to entertain a declaratory judgment action." *Elecs for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345 (Fed. Cir. 2005) (citations and internal quotation marks omitted). As discussed above, declining jurisdiction over Mylan's claim would undermine the Hatch-Waxman Act's policy of early resolution of patent disputes. *Purdue*, 2014 WL 1394178, at *9; *Shire*, 2012 WL 12919474, at *5. Thus, I do not recommend that the Court exercise its discretion to decline jurisdiction over Mylan's claim.

possibility (as opposed to 'reasonable likelihood') that the asserted claims could be invalidated [after an] appeal and [that this would] result in simplification is too speculative to be given much weight." (citation omitted); *Elm 3DS Innovations, LLC v. Samsung Elecs. Co.*, C.A. No. 14-1430, 2018 WL 1061370, at *1–2 (D. Del. Feb. 26, 2018) (same)).

The first factor favors Mylan. A stay would not simplify the issues because Defendants' appeal to the Federal Circuit involves a different patent unrelated to the instant dispute, no additional facts would help this Court determine whether Mylan's ANDA Product infringes the '053 Patent, and Mylan asserts (and Defendants do not dispute) that Mylan's ANDA can be approved notwithstanding the '310 Patent because it "was not listed in the Orange Book in connection with Defendants' Xarelto® 2.5 mg tablets when Mylan submitted its ANDA." (D.I. 25 at 6 n.2).

The second factor slightly favors Defendants. No discovery has been taken and no trial date has been set. But as Defendants note, "we expect that if this [C]ourt were to decide that it had jurisdiction, that the resolution of this case would not require a significant amount of time." (Tr. 51:13–16).

The third factor favors Mylan. Without a judgment of non-infringement, FDA final approval of Mylan's ANDA will be delayed by a patent for which Defendants' conceded Mylan does not infringe. Even if I were to credit Defendants' assertion that the Federal Circuit typically resolves PTAB appeals within 15 months, prejudice to Mylan still results: 15 months from September 22, 2023, the date of Defendants' appeal,[20] is December 22, 2024—more than one month after the '053 Patent expires on November 13, 2024 and enters the pediatric exclusivity

[20] *Mylan Pharms. Inc. v. Bayer Pharma AG*, IPR2022-00517, Paper No. 71 (PTAB Sept. 22, 2023).

period. Defendants have no answer to this prejudice. Defendants' motion in the alternative for a stay is denied.

## IV. CONCLUSION

For the reasons set forth above, I recommend that Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction be DENIED.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), (C), Federal Rule of Civil Procedure 72(b)(1), and D. Del. LR 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the District Court.

The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated March 7, 2022, a copy of which can be found on the Court's website.

Dated: January 31, 2024

Laura D. Hatcher
United States Magistrate Judge